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PATENT  
8907/84445

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Jack BURGER et al.	Confirmation:	9138
Serial No.:	10/552,623	Art Unit:	1794
Filed:	October 15, 2005	Examiner:	N. Dees
For:	Oxygen stable active containing compositions		

**RESPONSE TO REQUIREMENT FOR RESTRICTION**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

January 21, 2009

Sir:

Applicants respond to the Requirement for Restriction mailed December 17, 2008, which required election of one of the following groups of claims:

Group I, claims 1-14 and 16-21;

Group II, claim 15; or

Group III, claim 22.

Applicants appreciate the Examiner has indicated that the restriction between the product and process claims is subject to the possibility of rejoinder assuming, as specified on pages 3 and 4 of the Office Action, the non-elected process claims include the limitations of any allowable product claims.

While Applicants appreciate the Examiner's consideration of PCT procedures, favorable reconsideration and withdrawal of the restriction requirement is nonetheless courteously solicited. The unity of invention rules were necessarily considered with respect to the PCT application and it was determined that *all* claims can, should, and indeed were examined in one application.

First, the International Search Report, a copy of which is of record, considered **all** claims. Thus, under the PCT guidelines, the International Searching Authority had no problem considering, and issuing a search report based on, all claims.

Second, the PCT International Preliminary Report on Patentability issued October 14, 2005, which is accessible to the USPTO, nowhere reported lack of unity of invention. This is clearly demonstrated on page 2 of the Report where **all** claims were addressed.

Third, the Written Opinion of the International Searching Authority reported that the inventions defined by **all** of claims 1-22 had novelty, possessed inventive step and industrial applicability; or, in U.S. vocabulary, the claims were not anticipated, were unobvious, and had utility. See attached.

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**Box No. V Reasoned statement under Rule 43b/s.1(a)(I) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	1-22
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	1-22
Industrial applicability (IA)	Yes: Claims	1-22
	No: Claims	

Accordingly, Applicants submit the evidence demonstrates all claims can and should be examined together, and there is no substantial evidence to support a restriction requirement, whether under U.S. practice or under the PCT unity-of-invention rules. Indeed, the latter need not be reprised since, as noted above, the International Searching Authority has already examined all of the claims and issued an appropriate report.

The foregoing traverse notwithstanding, Applicants hereby provisionally elect the claims defined by Group I, claims 1-14 and 16-21.

Applicants courteously request a favorable first action on the merits, accompanied by acknowledgment that the Examiner has received, entered into the record, and considered the information set forth in the International Search Report and International Preliminary Examination Report.

To the extent necessary during prosecution, Applicants hereby request any required extension of time not otherwise requested and hereby authorize the Commissioner to charge any required fees not otherwise authorized, including application processing, extension, and extra claims fees, to Deposit Account No. 06-1135 regarding our order number 8907/80017.

Respectfully submitted,

**FITCH, EVEN, TABIN & FLANNERY**

By 

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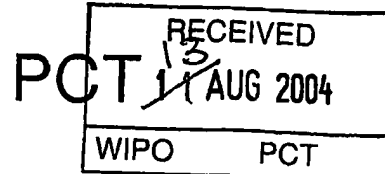
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To:

see form PCT/ISA/220

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY  
(PCT Rule 43bis.1)

Date of mailing  
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No.  
PCT/NL2004/000231

International filing date (day/month/year)  
08.04.2004

Priority date (day/month/year)  
08.04.2003

International Patent Classification (IPC) or both national classification and IPC  
A23L1/22, A23P1/04, A61K9/16, C08L1/28

Applicant  
QUEST INTERNATIONAL B.V.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**Box No. I Basis of the opinion**

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1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
  - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:
    - ☐ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material:
    - ☐ in written format
    - ☐ in computer readable form
  - c. time of filing/furnishing:
    - ☐ contained in the international application as filed.
    - ☐ filed together with the international application in computer readable form.
    - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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**Box No. II Priority**

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1. ☒ The following document has not been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

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**Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	1-22
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	1-22
Industrial applicability (IA)	Yes: Claims	1-22
	No: Claims	

2. Citations and explanations

**see separate sheet**

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Reference is made to the following documents:

- D1: WO 02 47492 A (BURGER JACK ;DOORN LOUIS (NL); CAMPANILE FABIO (NL); CORDA GIUSEPP) 20 June 2002 (2002-06-20)
- D2: US-A-4 534 983 (KOENE CASPER H ET AL) 13 August 1985 (1985-08-13)
- D3: WO 96 25150 A (NANOSYSTEMS LLC) 22 August 1996 (1996-08-22)
- D4: EP-A-1 252 829 (TAKASAGO INTERNAT CORP) 30 October 2002 (2002-10-30)
- D5: US-A-6 056 949 (MENZI HEINI ET AL) 2 May 2000 (2000-05-02)
- D6: WO 00 36931 A (UHLEMANN JENS ;BOECK REINHARD (DE); HAARMANN & REIMER GMBH (DE); H) 29 June 2000 (2000-06-29)
- D7: US-A-6 056 992 (LEW CHEL W) 2 May 2000 (2000-05-02)
- D8: DE 199 42 581 A (HAARMANN & REIMER GMBH) 30 March 2000 (2000-03-30)

**2. Novelty and inventive step**

2.1 None of the prior art documents discloses a composition and the products comprising it according to independent claims 1 and 16, nor the process for its manufacture according to independent claim 15. Namely, the claimed composition, products and process differ from those of D1 by the addition of the modified cellulose coating. Lastly, the use according to independent claim 22 is not disclosed in D1 and differs from the uses of D4 and D5 by the inclusion of the characteristics of the composition. Thus, the claimed subject-matter is new (Art. 33 (2) PCT).

2.2 As correctly mentioned by the Applicant in the description, when document D1 is taken as the closest prior art, the claimed composition, product, process and uses differ from those of D1 by the addition of the modified cellulose coating. The new objective problem to be solved in light of D1 is therefore to provide a solution for an improved protection of the encapsulated material for improved oxygen stability. However, not only would it appear obvious for a man skilled in the art that a further coating improves the protection of the encapsulated compound, but such protective coatings consisting of cellulose ethers are suggested by D4, also for the protection

against oxydation (see more specifically §1-3, 5, 29). Same also applies to D5 (see more specifically col.2 li.40-44).

The same reasoning can be held starting from D2 (example 2) as the closest prior art, with D4 or D5 suggesting the further coating with a cellulose ether.

The claimed subject-matter might also be seen as the provision of an alternative coating to that disclosed in D3, where the protective coating comprises PVP and PEG (see more specifically p.3 li.23-32, p.9 li.9-12). Again, an alternative coating of cellulose ethers is suggested by D4-D5.

Lastly, the possibility of applying a further fat coating over the modified cellulose coating has to be seen as mere obvious option for the skilled person, as its effect falls within the expectations of the skilled person.

2.2 Thus, none of the claims 1-22 can be deemed to involve an inventive step in the sense of Art. 33 (3) PCT. However, the above objections might be overcome if the Applicant were able to convincingly prove that the modified cellulose coating indeed provides unexpected effects as regards the protective effect. This should best be done by providing data of comparative tests, e.g. where different types of coatings are tested.

2.3 The most relevant parts of the above cited prior art documents are those identified in the International Search Report, to which the Reader is referred.

3. The subject-matter of all claims is industrially applicable in the sense of Art. 33 (4) PCT.

### **Re Item VIII**

#### **Certain observations on the international application**

VIII.1 A simple clarity issue (Art. 6 PCT) arises for claim 4, where the matrix is said to comprise 1 to 30% of the polyol sweetener, whereas in claim 1 (to which claim 5 refers) the minimum level for that compound is 5%.